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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/908,994	07/17/2001	John Shigeura	4470	8729

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MILA KASAN, PATENT DEPT.  
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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1634

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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## Office Action Summary

Application No.

09/908,994

Applicant(s)

SHIGEURA ET AL.

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 10-14 and 16-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-14 and 16-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 March 2004 has been entered.

### *Specification*

1. The specification is objected to as documents have been improperly incorporated by reference. In particular, the specification states at page 26:

All documents cited herein are incorporated herein by reference to the same extent as if each individual document was specifically and individually indicated to be incorporated by reference.

Such omnibus language fails to specify what specific information applicant seeks to incorporate by reference and similarly fails to teach with detailed particularity just where that specific information is to be found in each of the cited documents. As set forth in *Advanced Display Systems Inc. v. Kent State University* (Fed. Cir. 2000) 54 USPQ2d at 1679:

Incorporation by reference provides a method for integrating material from various documents into a host document--a patent or printed publication in an anticipation determination--by citing such material in a manner that makes it clear that the material is effectively part of the host document as if it were explicitly contained therein. *See General Elec. Co. v. Brenner*, 407 F.2d 1258, 1261-62, 159 USPQ 335, 337 (D.C. Cir. 1968); *In re Lund*, 376 F.2d 982, 989, 153 USPQ 625, 631 (CCPA 1967). **To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that**

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**material is found in the various documents.** See *In re Seversky*, 474 F.2d 671, 674, 177 USPQ 144, 146 (CCPA 1973) (providing that incorporation by reference requires a statement “clearly identifying the subject matter which is incorporated and where it is to be found”); *In re Saunders*, 444 F.2d 599, 602-02, 170 USPQ 213, 216-17 (CPA 1971) (reasoning that a rejection or anticipation is appropriate only if one reference “expressly incorporates a particular part” of another reference); *National Latex Prods. Co. v. Sun Rubber Co.*, 274 F.2d 224, 230, 123 USPQ 279, 283 (6<sup>th</sup> Cir. 1959) (requiring a specific reference to material in an earlier application in order to have that material considered a part of a later application); cf. *Lund*, 376 F.2d at 989, 13 USPQ at 631 (holding that **a one sentence reference to an abandoned application is not sufficient to incorporate from the abandoned application into a new application**). (Emphasis added.)

Accordingly, the cited documents are not considered to have been properly incorporated by reference and as such, have not been considered with any effect towards their fulfilling, either in part or in whole, the enablement, written description, or best mode requirements of 35 USC 112, first paragraph.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 10-14 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,124,092 (O'Neil et al.).

6. For convenience, claim 10, the only independent claim, is reproduced below.

10. A method for isolating one or more different-sequence polynucleotides from a mixture, the method comprising:

(a) flowing the mixture through a flow path containing a plurality of solid supports which are located in series in the flow path, each support having bound thereto a sequence-specific capture agent complementary to a different-sequence polynucleotide, under conditions effective to specifically bind different-sequence polynucleotides to corresponding sequence-specific capture agents on one or more of the supports,

(b) after said specific binding, releasing bound polynucleotides from a selected support by altering a physical property of that support while leaving unaltered the same physical property of at least one other of the supports,

(c) eluting the released polynucleotides through the flow path such that the eluted polynucleotides can be isolated in separated form.

7. For purposes of examination claim 10 has been interpreted as encompassing the isolation of from one to an infinite number of nucleic acid sequences, and that at a minimum, two different capture moieties are to be present and are bound at two different locations on a support

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that can virtually any shape but can act as a flow path for a mixture of nucleic acids capable of flowing.

8. O'Neil et al., disclose a method by which nucleic acids are immobilized to an addressable solid support through nucleotide sequence-specific binding and are in turn released from their solid support in a specific manner.

9. O'Neil et al., teach the use of "recovery tags," which, as found at column 15, last paragraph, are preferably polynucleotides.

10. Column 16, bridging to column 17, discloses various forms that the solid support may take, including arrays and beads.

11. The bound nucleic acids may be sequencing ladders, as well as amplification products; see column 19.

12. Column 14 discloses separating sequencing ladders separately from the amplification product that is also bound to the solid support. Column 18, last paragraph, discloses separating the amplification product from the support while allowing for the ladder to remain attached.

13. Column 15 discloses that selective separation of amplification product or ladder can be achieved through various means, including denaturation as well as enzyme cleavage, noting that restriction enzymes and nucleases can be used.

14. The aspect of using a "flow path" (claim 10) is met by the disclosure of using capillary channels (column 4, lines 48-49).

15. In view of the disclosures of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to have modified the method of O'Neil et al., such that one would have been able to have isolated one or more nucleic acids

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from a mixture of same whereby nucleic acids are immobilized to a solid support in an addressable manner and are released from said solid support through the altering of a physical property (temperature). In view of the detailed disclosure, and wide applicability, the ordinary artisan would have been amply motivated and would have had a most reasonable expectation of success.

16. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neil et al. (US Patent 6,124,092) as applied to claims 10-14 and 16-20 above, and further in view of Hellyer et al. (US Patent 6,207,818 B1).

17. See above for the basis of the rejection as it pertains to the disclosure of O'Neil et al.

18. O'Neil et al., does not disclose using voltage so to alter a physical property.

19. Hellyer et al., disclose a method of effecting stringency of hybridization conditions whereby one or more nucleic acids are immobilized to a solid support such as an array through manipulation of the voltage at specific sites on the support (see columns 3-4). Accordingly, one of skill in the art can manipulate hybridization conditions through voltage on parallel with that of temperature manipulation.

20. In view of the disclosures of the prior art of record, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of O'Neil et al., by substituting temperature modulation with voltage modulation as such allows for precise control of stringency at the various positions on an array. In view of the detailed guidance provided, the ordinary artisan would have reasonably expected to analyze and manipulate one or more samples in a simultaneous manner (see column 4 where "electronic

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multiplexing” is disclosed). Said ordinary artisan would have also been so motivated as “[t]he use of electronics in this technology provides increased versatility and flexibility over such conventional methods” (column 4, second paragraph).

21. For the above reasons, and in the absence of convincing evidence to the contrary, the claims are rejected as being obvious in view of the prior art of record.

Response to argument

22. At page 2 of the response of 31 March 2004, hereinafter the response, argument is advanced that the claimed method is distinguished over the teachings of O’Neil et al., in that the prior art “does not teach or suggest the arrangement of ‘a plurality of solid supports in series in a flow path, each support having bound thereto a sequence-specific capture agent complementary to a different sequence polynucleotide’” (emphasis in the original).

23. At column 3, penultimate paragraph, O’Neil teaches explicitly of having amplification products (applicant’s polynucleotide mixture) bind to complementary sequences that have been immobilized to “one or more solid supports.” The aspect that the polynucleotide mixture is able to flow over the one or more solid supports such that polynucleotides in solution are able to come into contact with the one or more solid supports meets the limitation that the one or more solid supports are in a flow path.

24. At page 2, bridging to page 3 of the response applicant asserts that O’Neil et al., have but one recovery tag per capillary channel, and that O’Neil does not teach or suggest the arrangement of a plurality of solid supports in series in a single capillary channel i.e.- flow path).”



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25. The argument has been fully considered and has not been found persuasive for as shown above, O'Neil does teach and suggest using a plurality of solid supports so to immobilize or capture specific polynucleotides out of a mixture of same.

26. Therefore, and in the absence of convincing evidence to the contrary, claims 10-14 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,124,092 (O'Neil et al.).

### *Conclusion*

27. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

28. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however,

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will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

29. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751.

The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

31. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

BLS  
14 April 2004